New U.S. National Phase Application Based on PCTUS03/19652

Preliminary Amendment dated December 20, 2004

Attorney Ref. No.: 037003 - 0313985

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## IN THE CLAIMS:

This listing of claims will replace all prior versions, and listings, of claims in the application. Claims 2-21, 83-101, and 103-121 are canceled.

1. (Original) A concentrated antibody composition consisting essentially of an aqueous solution of antibodies and histidine or acetate buffer at a concentration in the range of from about 2 mM to about 48 mM.

## 2-21. (Canceled)

- 22. (Original) A method for producing a concentrated antibody preparation comprising the steps of:
- a) providing an initial antibody preparation consisting essentially an aqueous solution of antibodies and histidine or acetate buffer at a concentration in the range of from about 2 mM to about 48 mM; and
- b) subjecting the initial antibody preparation to membrane filtration that removes water and buffer but not antibodies from the antibody preparation,

thereby producing an antibody preparation having a higher concentration of antibodies than the initial antibody preparation.

- 23. (Original) The method of claim 22, wherein the concentration of histidine or acetate buffer in the initial antibody preparation is in the range of from about 3 mM to about 48 mM.
- 24. (Original) The method of claim 22, wherein the concentration of histidine or acetate buffer in the initial antibody preparation is in the range of from about 4 mM to about 45 mM.
- 25. (Original) The method of claim 22, wherein the concentration of histidine or acetate buffer in the initial antibody preparation is in the range of from about 5 mM to about 40 mM.

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26. (Original) The method of claim 22, wherein the concentration of histidine or acetate buffer in the initial antibody preparation is in the range of from 20 mM to 25 mM.

- 27. (Original) The method of claim 22, wherein the pH of the initial antibody preparation is in the range of from about 4.0 to 7.5.
- 28. (Original) The method of claim 22, wherein the pH of the initial antibody preparation is in the range of from 4.5 to 7.0.
- 29. (Original) The method of claim 22, wherein the pH of the initial antibody preparation is in the range of from 5.0 to 6.5.
- 30. (Original) The method of claim 22, wherein the pH of the initial antibody preparation is in the range of from 5.5 to 6.0.
- 31. (Original) The method of claim 22, wherein the antibodies are monoclonal antibodies.
- 32. (Original) The method of claim 31, wherein the antibodies are chimeric antibodies comprising variable regions of a non-human species and human constant regions.
- 33. (Original) The method of claim 32, wherein the antibodies are chimeric antibodies comprising variable regions of an Old World monkey and human constant regions.
- 34. (Original) The method of claim 31, wherein the antibodies are humanized antibodies comprising hypervariable regions of a non-human species, at least one human framework region and human constant regions.
- 35. (Original) The method of claim 22, wherein the antibodies are of one or more of the isotypes selected from IgG, IgM, IgA, IgD, and IgE.
  - 36. (Original) The method of claim 35, wherein the antibodies are IgG antibodies.

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37. (Original) The method of claim 36, wherein the antibodies are IgG<sub>1</sub> or IgG<sub>4</sub> antibodies.

38. (Original) The method of claim 22, wherein the concentration of the antibodies

in the antibody preparation produced by step b) is at least 50 mg/ml.

39. (Original) The method of claim 22, wherein the concentration of the antibodies

in the antibody preparation produced by step b) is at least 100 mg/ml.

40. (Original) The method of claim 22, wherein the antibodies comprise

monoclonal antibodies selected from the group consisting of anti-CD80, anti-gp39, anti-CD4,

anti-CD23, and anti-CD20 antibodies.

41. (Original) The method of claim 22, wherein the antibodies comprise at least one

monoclonal antibody selected from the group consisting the anti-CD80 antibody IDEC-114,

the anti-gp39 antibody IDEC-131, the anti-CD4 antibody IDEC 151, the anti-CD23 antibody

IDEC-152, and the anti-CD20 antibody rituximab.

42. (Original) An improved method for producing a concentrated antibody

preparation comprising the steps of:

a) providing an initial antibody preparation consisting essentially of an aqueous

solution of antibodies and buffer; and

b) subjecting the initial antibody preparation to membrane filtration that removes

water and buffer but not the antibodies from the antibody preparation,

thereby producing an antibody preparation having a higher concentration of

antibodies than the initial antibody preparation;

the improvement consisting of using buffer selected from histidine or acetate at a

concentration in the range of from about 2 mM to about 48 mM.

43. (Original) The improved method of claim 42, wherein the concentration of

histidine or acetate buffer in the initial antibody preparation is in the range of from about 3

mM to about 48 mM.

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44. (Original) The improved method of claim 42, wherein the concentration of histidine or acetate buffer in the initial antibody preparation is in the range of from about 4

mM to about 45 mM.

45. (Original) The improved method of claim 42, wherein the concentration of

histidine or acetate buffer in the initial antibody preparation is in the range of from about 5

mM to about 40 mM.

46. (Original) The improved method of claim 42, wherein the concentration of

histidine or acetate buffer in the initial antibody preparation is in the range of from 20 mM to

25 mM.

47. (Original) The improved method of claim 42, wherein the pH of the initial

antibody preparation is in the range of from about 4.0 to 7.5.

48. (Original) The improved method of claim 42, wherein the pH of the initial

antibody preparation is in the range of from 4.5 to 7.0.

49. (Original) The improved method of claim 42, wherein the pH of the initial

antibody preparation is in the range of from 5.0 to 6.5.

50. (Original) The improved method of claim 42, wherein the pH of the initial

antibody preparation is in the range of from 5.5 to 6.0.

51. (Original) The improved method of claim 42, wherein the antibodies are

monoclonal antibodies.

52. (Original) The improved method of claim 51, wherein the antibodies are

chimeric antibodies comprising variable regions of a non-human species and human constant

regions.

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53. (Original) The improved method of claim 52, wherein the antibodies are chimeric antibodies comprising variable regions of an Old World monkey and human

constant regions.

54. (Original) The improved method of claim 51, wherein the antibodies are

humanized antibodies comprising hypervariable regions of a non-human species, at least one

human framework region and human constant regions.

55. (Original) The improved method of claim 42, wherein the antibodies are of one

or more of the isotypes selected from IgG, IgM, IgA, IgD, and IgE.

56. (Original) The improved method of claim 55, wherein the antibodies are IgG

antibodies.

57. (Original) The improved method of claim 56, wherein the antibodies are IgG<sub>1</sub>

or IgG<sub>4</sub> antibodies.

58. (Original) The improved method of claim 42, wherein the concentration of the

antibodies in the antibody preparation produced by step b) is at least 50 mg/ml.

59. (Original) The improved method of claim 42, wherein the concentration of the

antibodies in the antibody preparation produced by step b) is at least 100 mg/ml.

60. (Original) The improved method of claim 42, wherein the antibodies comprise

monoclonal antibodies selected from the group consisting of anti-CD80, anti-gp39, anti-CD4,

anti-CD23, and anti-CD20 antibodies.

61. (Original) The improved method of claim 42, wherein the antibodies comprise

at least one monoclonal antibody selected from the group consisting the anti-CD80 antibody

IDEC-114, the anti-gp39 antibody IDEC-131, the anti-CD4 antibody IDEC 151, the anti-

CD23 antibody IDEC-152, and the anti-CD20 antibody rituximab.

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62. (Original) A method for producing a pharmaceutical composition comprising antibodies as the active ingredient, comprising the steps of:

a) providing an initial antibody preparation consisting essentially of an aqueous solution of antibodies and histidine or acetate buffer at a concentration in the range of from about 2 mM to about 48 mM; and

- b) subjecting the initial antibody preparation to membrane filtration that removes water and buffer but not antibodies from the antibody preparation, thereby producing an antibody preparation having a higher concentration of antibodies than the initial antibody preparation; and
- c) combining antibodies of the concentrated antibody preparation of step b) with one or more pharmaceutically acceptable carriers to produce a pharmaceutical composition.
- 63. (Original) The method of claim 62, wherein the concentration of histidine or acetate buffer in the initial antibody preparation is in the range of from about 3 mM to about 48 mM.
- 64. (Original) The method of claim 62, wherein the concentration of histidine or acetate buffer in the initial antibody preparation is in the range of from about 4 mM to about 45 mM.
- 65. (Original) The method of claim 62, wherein the concentration of histidine or acetate buffer in the initial antibody preparation is in the range of from about 5 mM to about 40 mM.
- 66. (Original) The method of claim 62, wherein the concentration of histidine or acetate buffer in the initial antibody preparation is in the range of from 20 mM to 25 mM.
- 67. (Original) The method of claim 62, wherein the pH of the initial antibody preparation is in the range of from about 4.0 to 7.5.
- 68. (Original) The method of claim 62, wherein the pH of the initial antibody preparation is in the range of from 4.5 to 7.0.

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69. (Original) The method of claim 62, wherein the pH of the initial antibody preparation is in the range of from 5.0 to 6.5.

70. (Original) The method of claim 62, wherein the pH of the initial antibody preparation is in the range of from 5.5 to 6.0.

71. (Original) The method of claim 62, wherein the antibodies are monoclonal antibodies.

72. (Original) The method of claim 71, wherein the antibodies are chimeric antibodies comprising variable regions of a non-human species and human constant regions.

73. (Original) The method of claim 72, wherein the antibodies are chimeric antibodies comprising variable regions of an Old World monkey and human constant regions.

74. (Original) The method of claim 71, wherein the antibodies are humanized antibodies comprising hypervariable regions of a non-human species, at least one human framework region and human constant regions.

75. (Original) The method of claim 62, wherein the antibodies are of one or more of the isotypes selected from IgG, IgM, IgA, IgD, and IgE.

76. (Original) The method of claim 75, wherein the antibodies are IgG antibodies.

77. (Original) The method of claim 76, wherein the antibodies are  $IgG_1$  or  $IgG_4$  antibodies.

78. (Original) The method of claim 62, wherein the concentration of the antibodies in the antibody preparation produced by step b) is at least 50 mg/ml.

79. (Original) The method of claim 62, wherein the concentration of the antibodies in the antibody preparation produced by step b) is at least 100 mg/ml.

80. (Original) The method of claim 62, wherein the antibodies comprise monoclonal antibodies selected from the group consisting of anti-CD80, anti-gp39, anti-CD4, anti-CD23, and anti-CD20 antibodies.

81. (Original) The method of claim 62, wherein the antibodies comprise at least one monoclonal antibody selected from the group consisting the anti-CD80 antibody IDEC-114, the anti-gp39 antibody IDEC-131, the anti-CD4 antibody IDEC 151, the anti-CD23 antibody IDEC-152, and the anti-CD20 antibody rituximab.

82. (Original) An improved method of therapy that includes the administration of a pharmaceutical composition comprising an antibody, the improvement comprising administering a pharmaceutical composition that is made by combining

an antibody preparation consisting essentially of an aqueous solution containing at least one therapeutically effective dose of an antibody and histidine or acetate buffer at a concentration in the range of from about 2 mM to about 48 mM that has been concentrated by membrane filtration, and

one or more pharmaceutically acceptable carriers to produce a pharmaceutical b) composition.

## 83-101. (Canceled)

102. (Original) A kit useful for the treatment of a mammal suffering from or predisposed to a disorder comprising at least one container containing a pharmaceutical composition that is the product of combining:

an antibody preparation consisting essentially of an aqueous solution containing at least one therapeutically effective dose of an antibody and histidine or acetate buffer at a concentration in the range of from about 2 mM to about 48 mM that has been concentrated by membrane filtration, and

one or more pharmaceutically acceptable carriers; b)

and further comprises a label or an insert indicating that said pharmaceutical composition may be used to treat said disorder.

## 103-121. (Canceled)